CCH Healthcare Compliance LETTER

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Letters to the Editor

The CCH Healthcare Compliance team welcomes comments regarding articles published in the CCH Healthcare Compliance Letter. Send comments to Jeff Reinholtz, Managing Editor at reinholj@cch.com. For more information about the CCH Healthcare Compliance Portfolio visit our online store at http://health.cch.com.

Input on preemption exceptions sought

by Raio G. Krishnayya, J.D. & Gordon R. Shea, J.D.

As healthcare entities gear up to comply with HIPAA's now finalized Privacy Rule, they may want to take a step back and consider that, thanks to a legal doctrine known as preemption, the rule may not even apply to them—or may apply only in part. *See "To ends the most public and universal:" Preemption and the Privacy Rule*, CCH Healthcare Compliance Letter, Vol. 5, Issue 19, Sept. 30, 2002.

In response to the growing healthcare industry concern over preemption problems, on March 3, 2003, the Department of Health and Human Services (HHS) Office of Civil Rights (OCR) issued a *Notice of Address for Submission of Requests for Preemption Exception Determinations*. The Notice for commentary comes in response to the legislative quandary created under §262 of HIPAA that asserts that federal law preempts state law with regard to HIPAA compliance. However, §1178(a)(2)(A) of the Social Security Act allows requests for preemption exceptions to made pursuant to certain criteria.

The Notice lays out the criteria for preemption exceptions (i.e. state law may be exempt from preemption) if:

- the state law is necessary,
- the state law prevents fraud and abuse in healthcare payments,
- the state law appropriately governs insurance or health plans,
- the state law addresses healthcare cost reporting, or
- the state law serves a compelling need related to public health, safety, or welfare, and the Secretary of HHS determines that an intrusion into covered material is warranted when balanced against the need to be served.

The Notice solicits commentary from all sources, but outlines specific guidelines from state entities that wish to comment on the proposed exceptions to preemption. The Notice specifies that if state entities seek to provide commentary, they must address specific issues such as: the specific standard for which the exception is being sought, a statement of how the exception would affect health care provider operations, a basis for why preemption should not apply to the state law, as well as other issues.

Comments regarding the preemption exceptions should be addressed to:

Director
Office of Civil Rights
Department of Health and Human Services
Mail Stop Room 506F
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201 ■

Notice, 68FR 11554, March 11, 2003, ¶155,013

Not-for-profit org. drafts Security Rule Accreditation Standard to aid in compliance

by Raio G. Krishnayya, J.D.

On February 20, 2003, the Department of Health and Human Services (HHS) issued the Final Security Rule for the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Rule becomes effective April 21, 2003, and most covered entities have until April 21, 2005, to become compliant. While this date seems a long way off, many agree that HHS's purpose in issuing the final Security Rule within close proximity of the final Privacy Rule was to ensure that both rules would operate as complimentary components of each other. As is the case with most HIPAA compliance, however, covered entities—their compliance and privacy officers, as well as legal consultants—are still attempting to determine, on a practical level, what constitutes HIPAA compliance.

To assist in reaching Security Rule compliance, the American Accreditation HealthCare Commission (URAC) has developed HIPAA Security Accreditation Standards, a document designed to allow HIPAA compliance officers a method for demonstrating what URAC calls "an indicator of good faith efforts to implement an effective HIPAA compliance program."

What is URAC? URAC is a not-for-profit organization founded in the early 1990s for the purpose of developing compliance standards for the healthcare industry. The organization is comprised of seven different programs ranging from research grant information to education and publication of compliance standards that would allow for URAC accreditation.

Security Accreditation. The Standard issued by URAC is designed for covered entities to assist in development of a Security Rule compliance program. Some of the goals as articulated by the guidance include:

- Guide internal verification of HIPAA security compliance efforts;
- Provide a method for documenting and conducting a due diligence review;
- Provide a source of industry security practices; and
- Support risk management efforts.

The format of the Accreditation Standards provides a general outline of the broad Security Rule requirements, and then gives specific suggestions for addressing each issue. For example, the Rule requires covered entities to "[i]mplement policies and procedures to ensure that all members of its workforce have appropriate access to electronic protected health information, as provided under paragraph (a)(4) of this section, and to prevent those workforce members who do not have access under paragraph (a)(4) of this section from obtaining access to electronic protected health information." Part of URAC's Accreditation Standard, which is in response to the Rule's requirement, suggests that covered entities "implement procedures for the authorization and/or supervision of workforce members who work with electronic protected health information...." Furthermore, the Standard suggests methods of terminating access in situations where an employee is allowed limited access to protected health information.

Is it enough? Although the Standard does address the compliance points of the Security Rule, the question still lingering is, what are the technological requirements to become compliant with the Security Rule? Many covered entities worry that Security Rule compliance may tax resources to protect health information. One commentator on the Security Rule, Vice President of Phoenix Health Systems, Tom Grove wrote:

> Numerous commenters noted that the Security standards should not be overly prescriptive because the speed with which technology is evolving could make specific requirements obsolete and deter technological progress. HHS responded by stating that standards should be defined in generic terms and should be scalable, flexible, and generally addressable through various approaches or technologies. The result is that the final rule offers more high-level guidance, providing what is essentially a model for information security, with less specific guidance on how to implement the model.

URAC has invited public commentary on its HIPAA Security Accreditation Standard. Commenters are requested to respond by April 9, 2003. A copy of URAC's HIPAA Security Accreditation Standards can be found at http://www.urac.org/urac_hipaas_10mar.doc. A copy of Tom Grove's comments regarding the HIPAA Final Security Rule can be found at http://www.hipaadvisory.com/regs/finalsecurity/summaryanalysis.htm. ■

CCH Chicago Bureau, March 10, 2003

CCH Healthcare Compliance LETTER

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Cost-sharing assistance plan for anti-rejection drugs implicates Anti-kickback statute

by Geraldine S. Stroka, J.D., R.N.

A pharmaceutical manufacturer cannot reimburse financially needy transplant patients for the Medicare co-payment amount incurred in connection with the use of its drug. The Office of Inspector General (OIG) determined that the manufacturer's proposed modification of its patient assistance program, to include transplant patients utilizing its immunosuppressive drug, would implicate the antikickback statute pursuant to the Social Security Act §1128B(b).

Medication-usage and cost. The pharmaceutical manufacturer produces a drug, cyclosporine, which suppresses a transplant patient's immune system to prevent rejection of the transplanted organ. Cyclosporine is administered immediately following transplant surgery and must be taken for the remainder of the patient's life. It had been the sole anti-rejection medication available until three other forms of the drug, determined to be therapeutically equivalent, were marketed.

A patient's annual cost for cyclosporine can be several thousand dollars. Until 2000, Medicare Part B paid for the drug for a maximum of 36 months. In 2000, Congress eliminated that time limitation and Medicare Part B began providing lifetime coverage for this drug.

Proposed program modification. Until Congress' action in 2000, the manufacturer, through its patient assistance program (PAP), provided the drug, free of charge, to financially needy uninsured patients including Medicare patients who had exhausted their 36 month limitation, met the income criteria, and lacked secondary insurance coverage. Once Medicare offered unlimited coverage, Medicare patients who had received the drug free-of-charge were required to pay an estimated yearly Medicare Part B copayment of $1,200.

The manufacturer proposed to modify its existing patient assistance program by reimbursing patients the Part B copayment amount instead of providing the drug, free of charge, to those patients who met PAP criteria. Under the modified PAP, transplant patients would have stricter financial guidelines than other patients in the program, but would have other advantages, such as the ability to obtain cyclosporine from any pharmacy. With the inclusion of the transplant patients in the modified PAP, the manufacturer planned to advertise the program to transplant physicians who routinely prescribe immunosuppressive drugs.

Applicable law. The OIG determined that the proposed arrangement, modifying the existing PAP, implicated the Anti-kickback statute. This statute makes it a criminal offense to knowingly and willfully offer, pay or solicit, or receive any remuneration to induce or reward referrals of items of services reimbursable by a federal healthcare program.

The OIG determined that this proposed arrangement posed a risk of both program and patient fraud and abuse for three main reasons. OIG stated that: (1) the proposed arrangement violated the statute because the manufacturer was paying Medicare patients for its drug, giving the manufacturer a financial advantage over its competitors; (2) the proposed arrangement would increase Medicare costs because Medicare patients had no financial liability and did not have any incentive to use the other drugs available; and (3) other alternatives, such as waiver of the copayment fee by the pharmacist supplying the medication, existed for financially-needy patients.

Importance. It is evident that the OIG will not permit arrangements by manufacturers, even ones targeting financially needy patients that would result in increased Medicare costs. It is also clear that the OIG expects that all parties, including patients, do their part to reduce healthcare costs in the federal healthcare programs. ■

OIG Advisory Opinion 03-2, Feb. 12, 2003, ¶150,200

Corporate governance: the snowballing physician-fee agreement problem (Part I of II)

by Raio G. Krishnayya, J.D.

An important issue in healthcare is market competition. But it can be misunderstood because liability ramifications are sometimes ignored, especially in comparison to the zeal of gaining a significant edge in the market. Conventional thought among healthcare providers is to assume that liability for unfair competition practices occurs primarily in the corporate world of goods and services. Recently, however, some healthcare providers have been forced to understand that the zeal in obtaining market advantages without consideration of competition liability can lead to damaging prosecution. Enter the concept of corporate governance.

Corporate governance is a broad topic and has previously been covered in a different subject (i.e. document retention policies in light of Enron).[1] While the concept of corporate governance is a broad topic, it is easier to understand this topic as 'liability avoidance.' This article is designed to address the issue of "liability avoidance" in a different healthcare issue—physician-fee agreements between provider organizations and participating-physicians. Specifically, the purpose of this article is to highlight how such agreements can implicate anti-trust, anti-kickback, and successor liability problems, thus stressing the importance of routine auditing and due diligence reviews.

Anti-trust. Anti-trust compliance is often missed as a frontline issue in the healthcare compliance arena. However, as the trend to develop strong corporate governance programs grows, the need to consider this issue develops into paramount importance. As Mountain Health Care, P.A. (MHC) of North Carolina discovered, failure to consider the ramifications of physician arrangements can be disastrous. The case began in the U.S. District Court for the Western District of North Carolina, *United States v. Mountain Health Care, P.A.*, and filed in late 2002, centered on the creation of a uniform fee schedule for participating physicians that resulted in violation of Section 1 of the Sherman Act.[2]

MHC is a preferred provider organization that was established in 1994 with its headquarters in Asheville, North Carolina. It boasts a network of over 1,800 healthcare providers across North Carolina, as well as a myriad of services from home health services to optometrists and urgent care facilities. Interestingly, MHC is entirely owned by participating physicians, although not all participating physicians are owners.[3]

As part of its business practice, MHC sells its physician network to managed care purchasers. As part of the physician network plan, MHC established a uniform fee schedule, which, as the name would imply, set a standard fee for services applicable to all participating physicians. The result of this uniform fee schedule, along with the widespread participation by solo-practicing physicians, was that physicians could provide services well below the customary fees. This, in turn, resulted in many managed care purchasers being forced to enter agreements with only MHC providers, since the lowered rates would amount to significant savings for the managed care enrollees.[4] The importance of this fact must be stressed, because as will be seen shortly, this not only created an anticompetitive market, but also could impact other potential claims under slightly different circumstances.

The complaint filed by the government alleged that the uniform fee schedule amounted to a violation of Section 1 of the Sherman Act. Section 1 broadly prohibits the formation of contracts, agreements, or trusts that are a "restraint of trade or commerce among the several States, or with foreign nations."[5] The uniform fee schedule allowed MHC to enter agreements with managed care purchasers at costs that would have resulted in significant savings to managed care enrollees. In a time when healthcare costs are exponentially rising, this scheme begs the question, 'what's wrong with that?'

The answer resides in the term used by the court: "price-setting organization."[6] Under Anti-trust law, any arrangement that involves mergers without the integration of resources for the purpose of affecting price is considered a *per se* violation of Section 1. This is critical in terms of the MHC situation.

As part of the Competitive Impact Statement, the court made a finding regarding this issue.

> Mountain Health Care did not engage in any activity that might justify collective agreements on the prices its members would charge for their services. Its participating physicians have not clinically or financially integrated their practices to create significant efficiencies to the benefit of managed care purchasers and their employees and enrollees.[7]

Final judgment in the case is pending public commentary to the U.S. Department of Justice Antitrust Division.[8]

The *Mountain Health Care* case illustrates several points to consider about competition. First, while the facts in *Mountain Health Care* indicate no malicious or criminal intent, MHC still found itself in the throes of major anti-trust litigation. This indicates that even innocent intentions can still lead to liability if the market advantage (i.e. physician-fee agreements) results in an atmosphere of anticompetitiveness. Second, the case illustrates that anti-trust cases are a big-ticket item for the government. There has been speculation that the war on terrorism will divert resources, resulting in diminutive federal intervention in other arenas like anti-trust. Not so. Consider the remarks of Timothy J. Muris, Chairman of the Federal Trade Commission (FTC), published at the joint Department of Justice (DOJ)/FTC hearings held in February of this year.

> [t]he Commission continues to see a wide variety of overt anticompetitive behavior in health care, along with some new variants. The Commission continues to bring cases against physicians alleging price fixing—much like those brought by the agency during the last 20 years—although several of the new cases involve an unprecedented number of doctors and consultants, who coordinated the conduct under the guise of assisting in negotiations with payors.[9]

Third, the *Mountain Health Care* case strikes at the heart of physician agreements—a commonplace entity in healthcare. MHC is certainly not in a unique position with regard to entering physician-fee agreements. Worse yet, government intervention in such cases give physician-fee agreements an erroneous air that healthcare providers are in collusion with physicians to create unfair competitive advantages. To the contrary, many physicians do not consider this an issue of price-fixing, but rather one of unequal bargaining power. Consider the remarks of Dr. Tim Doran of the American Academy of Pediatrics when he spoke at the hearings in February:

> The imbalance of power is evident in health plan contracting practices. As a practical matter, while physicians may have flexibility to set what they charge, this often has little or no correspondence to the payment level they actually receive. Because of their size, the vast majority of physician groups do not have an ability to negotiate with health plans. In actuality, many physicians report that there is no negotiating; they are expected to sign the contract as is.[10]

Anti-kickback implications. The uniform fee schedule implications raised in the MHC case, however, raise another question: whether a Section 1 violation could also violate the Medicare Anti-kickback statute. Note that no anti-kickback violation was alleged against MHC; however, the nature of MHC's operations, as well as the circumstances surrounding the Sherman Act violation, potentially sends a warning that a carefully crafted complaint could include an anti-kickback violation.

Consider if the facts of the *Mountain Health Care* case were slightly changed; namely replace Medicare intermediaries with managed care purchasers, thus adding a federal reimbursement element to the facts. This change makes it far more probable that the Anti-kickback statute would be implicated because the physician-fee agreements would allow a system like MHC to offer significant savings to entice Medicare beneficiaries.

The next part of this article considers the ramifications of the Medicare Anti-kickback statute under a hypothetical scenario, analogous to the *Mountain Health Care* case scenario, but with important changes in the fact pattern. The article concludes by tying together how anti-trust and anti-kickback liability could be implicated under the doctrine of **successor liability,** thereby stressing the importance of conducting routine audits as part of a corporate governance program.

Raio G. Krishnayya, J.D., is an Attorney Analyst and Writer for the CCH Healthcare Compliance Portfolio. Raio brings a broad background—from his formal education in molecular biology and genetics, to his prior law enforcement/prosecutorial background—to coverage of issues ranging from the federal False Claims Act and fraud and abuse to bioterrorism preparedness. Please direct questions or comments about this article to krishnar@cch.com or call Raio at (847) 267-7040.

1 See *Enroned: Document Retention Lessons from a Business Scandal*, CCH Healthcare Compliance Letter, Vol. 5, Issue 9 (May 13, 2002); *and also, Watchdogs, lapdogs, and jumped sharks: Compliance beyond Enron,* CCH Healthcare Compliance Letter, Vol. 5, Issue 21 (Oct. 28, 2002).

2 *United States v. Mountain Health Care, P.A.,* Civil No. 1:02CV288-T (W.D.N.C. filed Dec. 13, 2002). A copy of the compliant, stipulation, proposed final judgment, and competitive impact statement may be found at: http://www.usdoj.gov/atr/cases/mountain.htm.

3 *Id.*

4 *Id.*

5 15 U.S.C. § 1.

6 *United States v. Mountain Health Care, P.A.,* Civil No. 1:02CV288-T (W.D.N.C. filed Dec. 13, 2002).

7 *United States v. Mountain Health Care, P.A.,* Civil No. 1:02CV288-T (W.D.N.C. filed Dec. 13, 2002); Competitive Impact Statement at 4.

8 Notice, *U.S. v. Mountain Health Care Proposed Final Judgment and Competitive Impact Statement*, 68 FR 1478 (Jan. 10, 2003).

9 *Everything Old is New Again: Health Care and Competition in the 21st Century*, prepared remarks of Timothy J. Muris, Chairman of the Federal Trade Commission, Nov. 7, 2002.

10 *Testimony Before the Federal Trade Commission on Health Care and Competition Law and Policy,* by Tim Doran, M.D., FAAP on behalf of the American Academy of Pediatrics, Feb. 27, 2003.

DMEs must end telemarketer calls to Medicare patients

by Geraldine S. Stroka, J.D., R.N.

The Office of Inspector General (OIG) will not allow telemarketers of durable medical equipment (DME) suppliers to pressure Medicare beneficiaries into purchasing items that they do not want or need. Acting on information that DME suppliers were utilizing independent marketing firms to place unsolicited telephone calls to Medicare beneficiaries, the OIG has issued a Special Fraud Alert concerning this practice. This Alert serves to notify the healthcare provider community of the existence of these calls, despite the statutory prohibition against them.

Prohibition against unsolicited calls. Social Security Act §1834(a)(17) prohibits suppliers of durable medical equipment from making unsolicited telephone calls to Medicare beneficiaries regarding the furnishing of a Medicare covered item, unless the call falls within one of the statutory exceptions. The three exceptions to the prohibition are that: (1) the beneficiary has given written permission to the supplier to make contact by telephone; (2) the contact is regarding a covered item the supplier has already furnished the beneficiary; or (3) the supplier has furnished at least one covered item to the beneficiary during the preceding fifteen months. This prohibition against a DME contacting a beneficiary includes both direct contact by the DME and indirect contact through a third party acting on the DME's behalf.

No payment derived from unsolicited call. Social Security Act §1834(a)(17)(B) sets out the impact on payments for covered items sold as a result of any prohibited call. This section specifically prohibits any payment to a DME supplier who knowingly submits a claim that was generated from a prohibited telephone call.

DME responsible. A DME supplier is ultimately responsible for the marketing activities of any third party with which it contracts or has any business dealings. In addition, a DME supplier is also responsible for determining that any information purchased from third parties does not stem from a prohibited activity. If a claim is submitted for an item of service stemming from a prohibited solicitation, both the DME and the telemarketer are potentially liable for criminal, civil, and administrative penalties.

Importance. The entire area of pharmaceuticals and durable medical equipment is getting increased scrutiny from the federal government. OIG issued a compliance program for the durable medical equipment industry in 1999. Pharmaceutical manufacturers and the durable medical equipment industry await the OIG's final compliance program guidance for pharmaceutical manufacturers, which is scheduled to be issued this spring. It will be interesting to see how extensive that final guidance will be. ■

Notice, OIG-Publication of OIG Special Fraud Alert on Telemarketing by Durable Medical Equipment Suppliers, 68 FR 10254, ¶152,021; Compliance Program guidance for the Durable Medical Equipment, Prosthetics, Orthotics, and Supply Industry, July 6, 1999, ¶151,006

CMS increases 2003 physician fee schedule payment update

by Katherine Lerner, J.D., Contributing Editor

On February 28, 2003, the Centers for Medicare and Medicaid Services (CMS) published a Final Rule updating the Medicare physician fee schedule payment rates effective for the period from March 1 through December 31, 2003. As discussed in more detail below, CMS issued this Final rule in response to recent Congressional legislation authorizing CMS to revise certain data used to calculate the annual physician fee schedule update. The physician fee schedule conversion factor from March through December 31, 2003 will be $36.7856, an increase of 1.6 percent from the calendar year 2002 conversion factor. The anesthesia conversion factor for this period will be $17.05, an increase of 2.7 percent from 2002. All information in the February 28 Final rule related to the calendar year 2003 physician and anesthesia conversion factors supersedes the information contained in the prior Final rule that was published on December 31, 2002. All other provisions of the December 31, 2002, Final rule are unchanged by the February 28, 2003, Final rule.

Sustainable growth rate. In the December 31, 2002, physician fee schedule Final rule, CMS explained that it did not have statutory authority to use actual, after-the-fact, data to revise estimates used to calculate the sustainable growth rates (SGR) for fiscal years (FY) 1998 and 1999 for purposes of determining future updates to the physician fee schedule. The Consolidated Appropriations Resolution of 2003 (PubLNo 108-7), approved by Congress on February 13 and signed by the President on February 20, authorizes CMS to revise the SGRs for earlier fiscal years and apply those revisions to future physician fee schedule updates. For purposes of determining future physician fee schedule updates, CMS has announced that the SGR was 3.2 percent for FY 1998 and 4.2 percent for FY 1999, an increase of 1.7 percent for FY 1998 and 4.5 percent for FY 1999. The revised SGR calculations for FY 1998 and 1999 apply prospectively and do not have any effect on physician fee schedule payment rates for previous years. CMS is also increasing its estimate of the calendar year 2002 SGR by 0.2 percent to reflect the costs of the new diabetes self-management training benefit.

CMS estimates that the changes to the 2003 physician fee schedule update will increase Medicare expenditures for physicians' services by $1.1 billion in FY 2003, $2 billion in FY 2004, and $2.8 billion in FY 2005, or an estimated $15.7 billion over five years and $49.6 billion over ten years.

CMS has extended the deadline until April 14, 2003, for physicians and practitioners to make their 2003 Medicare participation decision. ■

CCH Chicago Bureau, Feb. 28, 2003

Counties and municipalities *are* "persons" under the FCA

by Raio G. Krishnayya, J.D.

Almost exactly one year ago, two cases, *U.S. ex rel. Chandler v. Cook County* and *U.S. ex rel. Dunleavy v. County of Delaware*, came down. At the heart of both cases was whether counties could be considered "persons" as contemplated under the civil False Claims Act (FCA), and subsequently subject to the FCA treble damages clause. On March 10, 2003, the United States Supreme Court provided the final word on this issue, which caused a division among the federal circuits.

The Supreme Court heard and decided the *Chandler* case, determining that counties **are** "persons" as contemplated under the FCA, and furthermore, that counties are subject to the treble damages provision. Interestingly, the Court's opinion closely follows the logic of the U.S. Court of Appeals for the Seventh Circuit with regard to the damages issue; however, the Supreme Court employs a different line of reasoning in articulating that counties are "persons." In addition, the Court's decision leaves open several questions in light of certain contradictory conclusions drawn in the pivotal case *Vermont Agency of Natural Resources v. U.S. ex rel. Stevens*. Finally, the *Chandler* outcome, as a practical matter, would seem to require Court involvement in the cases that are currently pending review and also depart from the holding in *Chandler* (namely *Dunleavy*).

Persons. The threshold question decided by the Court was whether counties are "persons" within the meaning of the FCA. Recall that the Seventh Circuit opinion answered this question by an in-depth examination of the legislative history of the FCA. Specifically, the Seventh Circuit focused on three separate provisions of the FCA's history: the Civil Investigative Demand (CID) provision, the "whistleblower" provision, and the changes to the damages provision.

Recall that the CID provision allows the Attorney General to issue a demand from any "person" that may have relevant information to a FCA investigation, to provide that information. With regard to the CID provision, the Seventh Circuit noted that the definition of "person" within that section included the phrase "political subdivision of a State." Inclusion of this phrase led the Seventh Circuit to conclude, "[a]lthough this definition does not demonstrate Congressional intent to impose liability on municipalities, it certainly does not support an inference that Congress intended them to be exempt."

Furthermore, the court noted, the "whistleblower" provision also included the phrase "political subdivision of a State" within its definition of "person." Therefore, the Seventh Circuit surmised that inclusion of such language could only logically relate to municipalities, since states were very clearly exempt from FCA liability.

As to the third element, the damages provision, Cook County originally asserted that consistent with the Supreme Court's holding in *Stevens*, a municipality, like the state, cannot be subjected to punitive damages. The FCA's treble damages clause states that a person who has violated the FCA is:

> liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person....

Thus the County's argument resided in the fact that this provision implied punitive damages that could be levied against a municipality—damages that under *Stevens* are impermissible. The Seventh Circuit disagreed stating that the limitations on the damages prevent the underlying problem presented in *Stevens*—that punitive damages would allow juries to delve into the deep tax-based pockets of states. In contrast, however, the limitations imposed under the FCA prevent just such a problem. Although, the Supreme Court essentially adopted the Seventh Circuit's line of reasoning, as a practical matter, one could argue that both courts engaged in legal hair splitting as will be discussed *infra*.

As noted earlier, the Supreme Court's decision deviated from the Seventh Circuit's analysis of applicability of the term "persons" as it applies to municipalities. Unlike the Seventh Circuit's review of the FCA legislative history and supporting provisions, the Supreme Court reviewed the genesis of how courts historically treated corporations and how this treatment led to an understanding that municipalities could be considered "corporations," similar to their private counterparts. This mode of analysis stemmed from the Court's finding that although the FCA does not define "person", that this term always and undisputedly included corporations as covered entities, to which municipalities are a subset.

> There is no doubt that the term then extended to corporations, the Court in 1826 having expressly recognized the presumption that the statutory term "person" "'extends as well to persons politic and incorporate, as to natural person whatsoever.'" *Cowles*, however, was not an extension of principle but a natural recognition of an understanding going back at least to Coke, *supra*, that municipal corporations and private ones were simply to species of "body politics and corporate," treated alike in terms of their legal status as persons capable of suing and being sued. [Citations omitted].

As to the punitive damages prong of the Supreme Court's holding that Cook County was a "person" as contemplated under the FCA, the Court essentially followed the Seventh Circuit's line of reasoning. The Court recognized that the issue pertaining to the damages clause was whether the damages were punitive and thus likely to allow juries to abuse the deep pockets of tax-payer-based entities, thus awarding disproportionately high damage awards. However, following the Seventh Circuit's reasoning, the Supreme Court noted that the limitations imposed by Congress on the damages was a safe-guard against the kind of deep-pocket damages that are characteristic of punitive damages. Furthermore, the Court noted that the mechanism for determining damages does not reside with juries, but with the courts themselves—an additional safeguard.

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Simply, the Supreme Court decision articulates that municipalities like Cook County are "persons" for FCA purposes. Thus, as a corollary, such municipal entities are subject to the damages clause of the FCA as well. However, this decision leaves two unanswered questions. First, as a practical matter, it may be hard to reconcile the *Chandler* decision with that of *Stevens* since many of the characteristics of a state are implied upon a municipality. Second, where does that leave cases such as *Dunleavy*?

Practical considerations. When CCH first reported on the Seventh Circuit's holding, the question of whether an entire class of potential FCA plaintiff's would be removed from FCA bite was pending. Clearly the Supreme Court's decision is designed to keep municipalities and counties within the target of the FCA. However, some may ask how the state, which according to *Stevens* has completely escaped FCA liability, can be so dramatically different from a plaintiff such as Cook County.

The answer is found, in part, in history when since the civil war, the states and the federal government were considered two separate jurisdictions. A municipality, although often parallel in its functions with the state, is not considered a separate jurisdiction for constitutional law purposes. The other part of the answer lies in the fact that the state, as a separate jurisdiction, has its roots in the Eleventh Amendment of the U.S. Constitution, which protects state sovereignty. Subsequently, the Supreme Court's perspective of state sovereignty issues is best reflected in *Stevens*:

> Our conclusion is buttressed by two other considerations that we think it unnecessary to discuss at any length: first, "the ordinary rule of statutory construction" that "if Congress intends to alter the usual constitutional balance between States and the Federal Government, it must make its intentions to do so unmistakably clear in the language of the statute," and second, the doctrine that statutes should be construed so as to avoid difficult constitutional questions. [Citations omitted].

As a practical matter, the American Hospital Association (AHA) reported that as of December 2002, the United States health care system is comprised of 5801 hospitals. 1,156 of these are classified as "State and Local Government Community Hospitals," or approximately 20 percent of the hospitals are state and local government operated. The AHA did not break this category down further. Under *Stevens*, however, a portion of those hospitals would be entirely exempt from FCA liability, whereas under the *Chandler* opinion, some of those hospitals would remain potential FCA defendants.

As to the issue of the what happens to cases like *Dunleavy*, the Supreme Court may have, in some sense, already decided the case vis-à-vis *Chandler*. Recall that although *Dunleavy* is factually not healthcare related, it presented the same issue with regard to municipality liability under the FCA. Part of the *Dunleavy* opinion stressed that exclusion of specific language indicating municipal liability indicated congressional intent to preclude municipalities from FCA liability:

> Ambiguity, however, is not enough for Dunleavy to carry the day. There is simply nothing in the FCA's text remotely manifesting a clear expression of Congress' intent to abrogate local governmental immunity against punitive damages under the Act. As a result, we hold that Congress did not intend to disturb local governmental immunity from punitive damages under the FCA by clearly including local governments within the meaning of the term "person."

The Supreme Court's decision in *Chandler* seems to have impliedly countered this point: "[i]nferring repeal from legislative silence is hazardous at best, and error seems overwhelmingly likely in the notion that the 1986 amendments wordlessly redefined 'person' to exclude municipalities. Congress could have done that, of course, but it makes no sense to suggest Congress did it under its breath."

Punitive. As a final note, it is worth mentioning the toned-down stance on the issue of whether the FCA damages are punitive. Considering that much of the argument about whether municipalities could be liable under the FCA because of the punitive nature of the damages, it is noteworthy to illustrate the distinction between the *Stevens* Court's treatment versus the *Chandler* Court's treatment of whether the damages provision is punitive.

The *Stevens* Court expressed a strong, unequivocal message that the treble damages imposed by the FCA are punitive in nature:

> Although this Court suggested that damages under an earlier version of the FCA were remedial rather than punitive, that version of the statute imposed only double damages and a civil penalty of up to $10,000 per claim. "The very idea of treble damages reveals an intent to punish past, and deter future, unlawful conduct, not to ameliorate the liability of wrongdoers."[Citations omitted].

The *Chandler* Court took a more equivocal stance towards the treble damages clause. Generally the *Chandler* decision, although conceding that part of the treble damages does have a punitive quality, determined that there were "compensatory traits" to this provision as well. This gives the appearance that the damages clause of the FCA has a sliding-scale feel—part punitive, part compensatory.

The importance of this distinction is not mere semantics. This sliding-scale distinction is partly what brought Cook County within the purview of the FCA. Conversely, the unequivocal view that treble damages were punitive is the factor that triggered the prohibition against federal punishment of states without express congressional intent.

The reason for the change in perspectives is uncertain. However, in the healthcare arena, while it may have been commonplace to view "state and local" run healthcare entities as synonymous, today there is a distinction to be made—a potentially very high-priced distinction. ■

Cook County, Illinois v. U.S. ex rel. Chandler, U.S.S.Ct., No. 01-1572, March 10, 2003, ¶300,162; Vermont Agency of Natural Resources v. U.S. ex rel. Stevens, U.S.S.Ct., No. 98-1828, May 22, 2000, ¶300,153; U.S. ex rel. Chandler v. Cook County, 7th Cir., Nos. 00-4110, 01-1810, Jan. 22, 2002, ¶301,445; U.S. ex rel. Dunleavy v. County of Delaware, 3rd Cir., No. 00-3691, Jan. 29, 2002, ¶301,446